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Legal Requirements

General

Depending on legal requirements for dental surgeries in different countries you may be required to carry out periodic consistency checks of the X-ray systems you have available. The various appliances include the X-ray source device, the image system (CCD-Sensor, storage plates with Scanner) and the image viewing system (e.g. software, PC-graphic board, diagnostic monitor etc).

Digital X-ray systems in dental surgeries within the Federal Republic of Germany in must be operated according to the following standards, test procedures as well as rules and regulations:

- QS-directions according to the X-ray Regulations (known as RöV)
- Constancy checks for X-ray appliances according to DIN 6868-5
- Quality assurance tests for image viewing systems (known as BWG) and according to DIN V 6868-57

Consistency checks

X-ray appliances

Consistency check of the X-ray source appliance and the image system using a test body according to DIN6868-5:

Check interval according to Paragraph §16 Section 3 RöV is every 4 weeks

Image reproduction system (Diagnostic monitor)

Only mandatory for diagnostic stations (but at least one diagnostic station must be at hand)!

Check interval

Every working day: Gray level test of the monitor using special Test Picture (z.B. SMPTE).

Every 4 weeks: resolution, geometry and color fidelity.

Acceptance check

The acceptance checks for the X-ray appliance and of the image reproduction equipment used for diagnosis must be carried out by a fully-trained technician before the equipment is used the first time (i.e. during commissioning) for producing X-ray exposures and diagnosis. All acceptance checks are checked by an official expertise.

All acceptance checks must be checked by an independent expert.

Partial Acceptance Checks

New acceptance checks, or under certain conditions a partial acceptance check, are necessary when fundamental technical changes have been carried out to the equipment (e.g. changing the monitor used for diagnosis, new PC etc.).

Extract of the ZVEI Brochure „Quality Checks on Image Viewing Equipment“

Component	If repaired or replaced	
	Recording in test report	Check
Image Viewing Equipment (IVE)	Yes	Partial Test - IVE
Graphic board	Yes	Partial Test - IVE
Graphic board operating parameters (resolution, no. of colors, frequency)	Yes	Partial Test - IVE
Ambient light *	Yes	No
* In dental terms: position, type of lighting, reduction of daylight and switch settings. Technical lighting checks are not necessary!		

Periodic Expertise

Every 5 years a check must be repeated carried out by an expert. This test will be carried out under the guidelines laid down in the X-ray Regulations (Germany =RöV) and at the intervals recommended for the digital X-ray equipment.



Authorities in each German federal state can set shorter or longer intervals!

The consistency checks to guarantee consistent picture quality using the X-ray system (X-ray appliance, image viewer) must be recorded and retained for possible inspection for a period of not less than two years.

A chronologically-ordered X-ray Control Book must be kept and patient-relevant X-ray doses must be recorded.

Minimum Technical Requirements

The monitor system used for diagnostic purposes must fulfil the minimum requirements set out in Table 1 below.

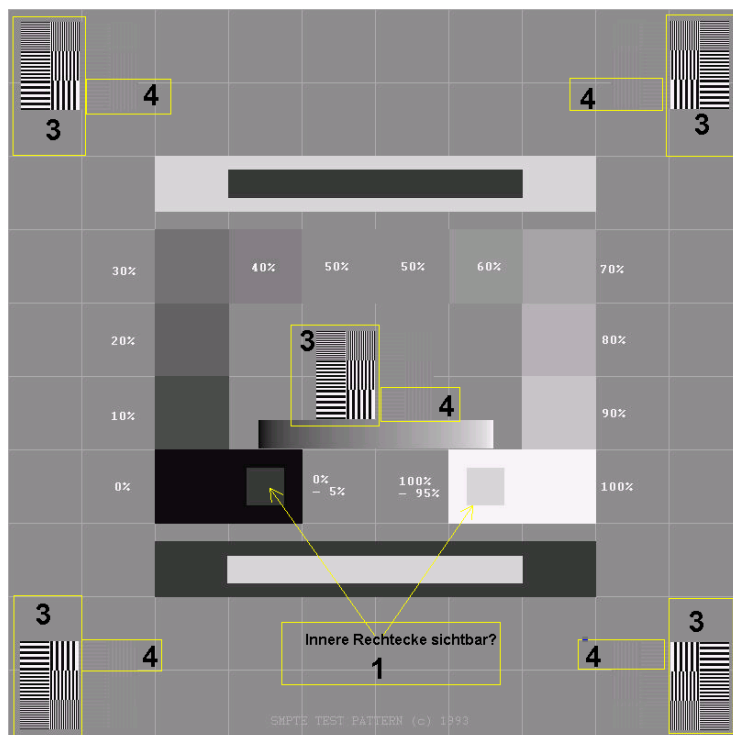
Table1: minimum requirements for diagnostic monitor system

Monitor plus graphic board	CRT (Cathode Ray Tube) monitor	TFT (LCD) Flat screen
Resolution	Shadow mask ≤ 0.28 mm	$\leq 0.30 \times 0.30$ pixel
Diagonal screen size Min. 370mm	$\geq 17"$	$\geq 15"$
Contrast ratio	$\geq 1:40$	$\geq 1:40$
Recurrence frequency	≥ 70 Hz	Not necessary
Screen matrix	$\geq 1024 \times 768$	$\geq 1024 \times 786$
Available diagonal size of the X-ray being viewed	≥ 200 mm	≥ 200 mm
Representation of 256 levels of gray (8-bit) Also possible with ≥ 24 bit color representation	+	+

Monitor test

A monitor test, for example using the SMPTE-Test picture, must be carried out under the regulations valid in the Federal Republic of Germany at least once every working day on at least one of the PC stations used in dental diagnosis.

SMPTE-Monitor test picture



Gray level reproduction

- (1) The two squares inside this area must be visible!
- (2) All rectangles where a percentage value is given between 0% and 100% must be visible and the equal steps in gray clarity must be discernible.

Resolution

- (3) 100% Modulation: All 6 rectangular line patterns must be visible, in both the centre and in the four corners!
- (4) 5% Modulation: both line patterns must be visible.

Geometry/Convergence

- (5) The background lattice lines have to run parallel over the whole screen, also in the edge areas.

Color Correctness

- (6) The lattice lines and homogenous gray value areas must not show color, this is valid also for edge areas.

Test	Test steps	
Each working day	1 + 2	
Every 4 weeks	3 + 4 + 5 + 6	

Testing with DBSWIN

Monitor check with DBSWIN

X-ray acceptance check with DBSWIN

X-ray consistency check with DBSWIN

Forms for carrying out Tests on X-ray facilities in Dental Medicine

Form	located on DBSWIN CD
Acceptance Tests for Image Viewing Equipment	<i>doku\formulare\Q_Bwg_Abnahmeformular.pdf</i>
Consistency Check for Image Viewing Equipment	<i>doku\formulare\ Q_Bwg_Konstanzformular_1Monat.pdf</i>
	<i>doku\formulare\ Q_Bwg_Konstanzformular_12Monate.pdf</i>
Acceptance Tests for X-ray systems	<i>doku\formulare\ Q_Xray_Abnahmeformular_intraoral.pdf</i>
	<i>doku\formulare\ Q_Xray_Abnahmeformular_extraoral.pdf</i>
Consistency Check for X-ray systems	<i>doku\formulare\Q_Xray_Konstanzformular.pdf</i>